

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas • PhytoPharmica  
Tyler Encapsulations Vitaline Formulas9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467**ENZYMATIC THERAPY®****&  
PHYTOPHARMICA®**825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 F: 920.469.4418 (Phyto)**ENZYMATIC THERAPY***What **Better** feels like.™*

2791 5 JUL 25 P2:21

July 13, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Vitaline Smart Q10 is recommended by cardiologists and neurologists for heart and brain health support.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

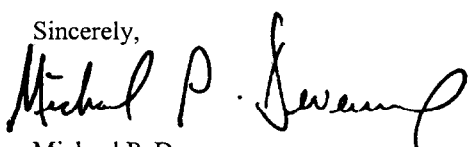
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/13/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Vitaline Smart Q10 is the first to be shown to be absorbed in both your bloodstream and your cells. That's critically important, because your brain and heart work 24/7 and rely on CoQ10's energy support.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Restores the CoQ10 depleted by most cholesterol lowering medications, including Zocor®, Pravachol® and Lipitor®.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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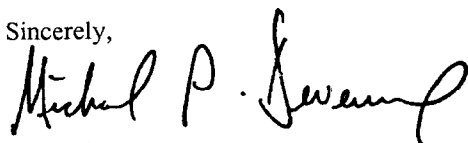
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Brands are registered marks of their respective companies.

Vitaline Smart:Q10 4e

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Dietary supplement clinically studied to support heart health.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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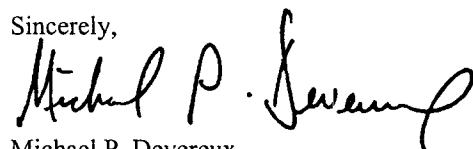
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	To be fully effective, CoQ10 must cross the cellular barrier and raise mitochondrial levels.	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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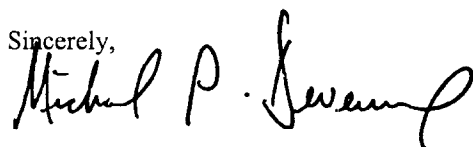
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	CoQ10 is essential for energy production.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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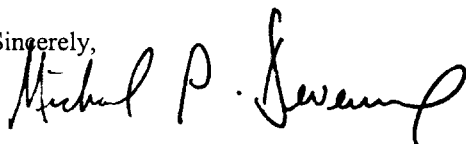
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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Vitaline® Smart CoQ10™	To produce energy, CoQ10 must cross cell membranes and raise mitochondrial levels of CoQ10. That's critical to cardiovascular health because each heart cell has up to 2,000 mitochondria-the highest concentration found anywhere in the body-and therefore has higher energy needs.	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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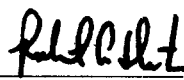
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Vitaline® Smart CoQ10™	CoQ10 also functions as a potent antioxidant.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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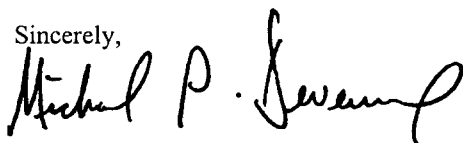
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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Vitaline® Smart CoQ10™	For it to be fully effective, it must cross the cellular membrane and raise the intracellular levels of CoQ10.	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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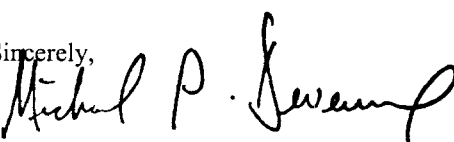
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Vitaline® Smart CoQ10™	In central nervous system applications, CoQ10 must pass the blood-brain barrier, resulting in increased brain intracellular levels to exert its effects.	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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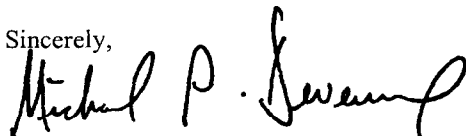
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Vitaline® Smart CoQ10™	Due to Vitaline Smart CoQ10 chewable's ability to pass through the cell membrane and enter the mitochondria, enhanced CoQ10 levels can be attained.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Through special processing techniques, Vitaline Smart CoQ10 chewable may be absorbed by the lymphatic system. This allows the CoQ10 to initially bypass the liver, resulting in increased absorption potential.	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

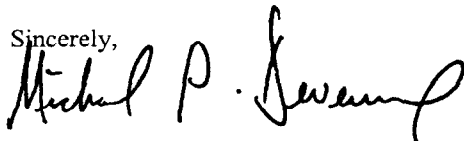
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/14/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
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&  
PHYTOPHARMICA®

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P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)



## ENZYMATIC THERAPY

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July 14, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	For individuals seeking neurological and movement support	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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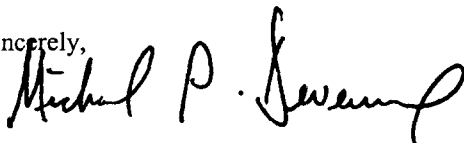
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Supports healthy neuronal activity.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

7/14/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Supports healthy levels of neurotransmitters in the brain.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

7/14/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® Smart CoQ10™	Enhances energy production in the mitochondria of the brain cells.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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By: \_\_\_\_\_

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Vitaline Smart CoQ10 18e





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July 15, 2005

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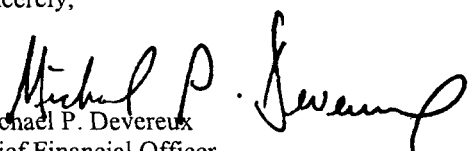
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